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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,058	11/02/2001	Henry K. Hui	JOHNA.049CP3	6464
27777	7590	03/31/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			JASTRZAB, KRISANNE MARIE	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 03/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/016,058

Applicant(s)

HUI ET AL.

Examiner

Krisanne Jastrzab

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Foller WO 91/05998 or Krahe GB 2,191,585 A in view of Pai et al., U.S. patent No. 6,156,267.

Both Foller and Krahe teach real-time monitoring of the concentration of an oxidizing sterilant within a sterilization enclosure by placement therein of a sensor formed from a material which exothermically reacts with the sterilant, creating temperature differential proportionate to the sterilant concentration. The sensor is electrically connected to monitor and control means such that the parameters of sterilization are adjusted based on the concentration information from the sensor. Both further teach the provision of two sensors, one providing the control, or ambient, information needed for the basis for comparison to the concentration sensor. The sensors are temperature sensitive, such as thermocouples or thermistors, which are coated with reactive material. Both references are silent as to the provision of the reactive sensor within a barrier enclosure. See page 1, lines 13-14, page 3, page 4, lines 1-5 and pages 8-9 of Foller. See page 1, lines 76-121, page 2, lines 35-50, page 3, lines 31-36 and lines 70-130 of Krahe.

Pai et al., teach the provision of sterilant concentration sensors within a barrier enclosure of a load-simulating device for real-time control of the sterilization process. The barrier enclosure is impermeable to microorganisms, while permeable to the sterilant vapor. The sensor, which can be a thermocouple configuration, is inserted within the barrier enclosure, while being electrically connected to the exterior of the sterilizer for interaction with the microprocessor control means to facilitate effective,

complete sterilization based on real-time measurement. The provision of the sensor within the enclosure allows for optimal determination of complete, effective sterilization such that the process can be timed with accurate precision. See column 3, lines 25-35, and lines 45-68, column 4, lines 42-50, column 5, lines 55-68, column 11, lines 1-15, and column 12, lines 20-25.

It would have been obvious to one of ordinary skill in the art to configure the placement of the sensors of either Foller or Krahe, within a barrier enclosure of a load-simulating device as taught in Pai et al., because it would ensure complete, effective sterilization because it would provide for control to account for all parameters of diffusion restricted devices to be sterilized.

#### ***Terminal Disclaimer***

The terminal disclaimer filed on 01/18/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on either application serial numbers 10/016,057 or 10/230,527 has been reviewed and is accepted. The terminal disclaimer has been recorded.

#### ***Response to Arguments***

Applicant's arguments, filed 1/18/2006, with respect to the terminal disclaimer filed to overcome the obviousness double patenting rejections have been fully considered and are persuasive. The obviousness double patenting rejections of all claims has been withdrawn.

Applicant's arguments filed 1/18/2006 concerning the art rejection of the claims, have been fully considered but they are not persuasive. Applicant argues that none of

the cited references teach the diffusion restricted area mimicking the lumen of a device, however, the Examiner would disagree and point to column 11, lines 55-62 of Pai et al., which clearly teaches the load –simulating device in the form of a lumened device.

***Conclusion***

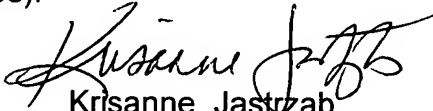
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne Jastrzab whose telephone number is 571-272-1279. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Krisanne Jastrab  
Primary Examiner  
Art Unit 1744

March 29, 2006